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NOTICE OF REASONS FOR REJECTION
(TRANSLATION)

Patent Application Number: 8-534940

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Applied Articles: Art. 29, Par. 2; Art. 36, Art. 37

It is deemed that this application should be rejected for the following reasons. Any argument should be submitted in writing within three months from the mailing date of this notice.

REASONS

1. This application does not satisfy the requirements prescribed in Article 37 of the Patent Law.
2. The claims are deemed defective on the points indicated below, and therefore this application does not satisfy the requirements prescribed in Article 36, Paragraph 6, Item 2 of the Patent Law.
3. The inventions described in the claims of this application, indicated in the remarks below, are ones which could be easily have been made, prior to the filing date of the present application, by a person skilled in the art to which the inventions pertain, on the basis of the inventions described in the publications, cited in the remarks below, distributed domestically or abroad prior to the filing date of the present application, and therefore are unpatentable

under the provisions of Article 29, Paragraph 2 of the Patent Law.

REMARKS (For the numbers of the cited references, etc.
see the List of Cited References.)

<Re Reason 1>

The invention according to claims 1 to 3 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein when aqueous humor flows through the tube passage, a bleb of aqueous humor forms under the conjunctiva.

The invention according to claim 4 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein the beveled surface of the inlet end lies in a first plane forming an angle with a longitudinal axis of the tube and the disk lies in a second plane which is angled opposite to the first plane.

The invention according to claim 5 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein the tube has a circumferential hole(s) which opens into the tube passage proximate the inlet end of the tube.

The invention according to claims 6 to 8 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein the disk comprises a base, an outer rim and an inner upright(s), and the base and outer rim form a reservoir.

The invention according to claims 9 to 11 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein the disk comprises a retention projection(s).

The invention according to claims 12 to 16 relates to an invention of a delivery device for implanting an intraocular implant.

The invention according to claims 17 to 24 relates to an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk, wherein the implant comprises an upright or a passageway.

As indicated in Reason 3 below, an invention of an intraocular implant comprising a tube which includes an inlet end, an outlet end and a tube passage, as well as a subconjunctival disk is described in reference 1, and therefore is not a novel feature. Thus, these seven inventions do not share a common problem to be solved which had not been solved at the filing date of the present application, and therefore they do not satisfy the requirement prescribed in Article 37, Item 1. Further, since these seven inventions do not share a common novel substantial part, they do not satisfy the requirement prescribed in Article 37, Item 2. Moreover, these seven inventions do not satisfy any of the requirements prescribed in Article 37, Items 3, 4 and 5.

<Re Reason 2>

The concrete meaning of the term "bleb" used in claim 1 is unclear.

Regarding the statement "the bleb and conjunctiva assist

in regulating the flow of aqueous humor through the tube passage" stated in claim 1, the manner of regulation is unclear.

The phrase "said conjunctiva" in claim 17 is deemed to be an error for --the conjunctiva--.

The concrete meaning of the phrase "a direction generally transverse to a longitudinal axis of the tube" in claims 18, 22 and 24 is unclear.

Accordingly, the inventions of claims 1 to 3, 17, 18, 22 and 24 are unclear.

<Re Reason 3>

Claims: 1 to 3

Cited References: 1

Notes

Reference 1 describes an insert member 21 (corresponds to the "intraocular implant" of the present invention) comprising a drainage passage 36 (corresponds to the "tube passage" of the present invention), a neck portion 23 (corresponds to the "tube" of the present invention) and a flange 24 (corresponds to the "subconjunctival" disk of the present invention), wherein the drainage passage 36 (tube passage) provides a path for the passage of fluids from the anterior chamber through the sclera and through the bleb of the conjunctiva outwardly into the body fluids. (See page 3, left-lower column, lines 11 to 21, page 4, left-upper column, lines 16 and 17, Figures 4A to 4D; Translator's comment: see the paragraph bridging pages 9 and 10, the first paragraph on page 13, as well as Figures 4A to 4D of the enclosed WO91/08784.)

Accordingly, the invention of claims 1 to 3 could be easily conceived of by a person skilled in the art on the

basis of the invention described in reference 1.

Claims: 4

Cited References: 1 to 4

Notes

Reference 2 describes an ophthalmic valve implant apparatus 28 (corresponds to the "intraocular implant" of the present invention) having a sharpened penetrant end 50 (corresponds to the "beveled surface" of the present invention). (See column 6, lines 17 to 28, Figures 1 and 2).

Reference 3 describes a plug (bouchon) having a flange 3 (collerette) (corresponds to the "disk" of the present invention) inclined relative to the longitudinal axis of the plug. (See page 2, right column, lines 22 to 23, Figure 1). Reference 4 describes a duct plug having a flange 1 (corresponds to the "disk" of the present invention) inclined relative to axis X of the duct plug. (See page 2, right-upper column, lines 11 to 12, Figures 1 to 3.) The "plug" of reference 3 and the "duct plug" of reference 4 are both for implantation into the human body, and therefore adjustment of the inclination of the disk of an implant for the human body so that it will fit the human body is a conventional technique. Therefore, inclining the disk so that it would fit the human body, as described in claim 4, is merely a matter of design variation.

Accordingly, the invention of claim 4 could be easily conceived of by a person skilled in the art on the basis of the inventions described in references 1 to 4.

Claims: 5

Cited References: 1, 5 and 6

Notes

Reference 5 describes an implant (corresponds to the "intraocular implant" of the present invention) having micro-

channels (correspond to the "circumferential holes" of the present invention) or an implant (corresponds to the "intraocular implant" of the present invention) having sections 146 cut out to increase outflow (correspond to the "circumferential holes" of the present invention). (See page 9, lines 25 to 30, Figure 9, page 10, lines 28 to 30, and Figures 14A to 14C.) Reference 6 describes a shunting tube having plural side holes 13 (correspond to the "circumferential holes" of the present invention). (See column 3, lines 6 to 26, Figures 1 to 3.)

Accordingly, the invention of claim 5 could be easily conceived of by a person skilled in the art on the basis of the inventions described in references 1, 5 and 6.

Claims: 6 to 8

Cited References: 1, 2 and 7

Notes

The invention described in reference 2 comprises a hollow crown 40 and an outside face 36 (corresponds to the "reservoir" of the present invention). (See column 6, lines 53 to 57, Figures 1 to 3.) It is deemed that forming a reservoir with a base and an outer rim or shaping it into a disk form is merely a matter of design variation. Further, reference 7 describes a reservoir 20 (corresponds to the "reservoir" of the present invention) defined by a posterior end 21, an anterior end 22, a peripheral baffling 23 (corresponds to the "outer rim" of the present invention). (See column 7, lines 35 to 38, Figure 1.)

Accordingly, the invention of claims 6 to 8 could be easily conceived of by a person skilled in the art on the basis of the inventions described in references 1, 2 and 7.

Claims: 9 to 11

Cited References: 1

Notes

See left-column, lines 16 to 19 (Translator's comment: page 9, the last line to page 10, line 7 of the enclosed WO91/08784), Figures 4A to 4D. The "flange 25" corresponds to the "retention projection" of the present invention.

Also, constructing the retention projection from a shape memory alloy could be easily accomplished by a person skilled in the art.

Accordingly, the invention of claims 9 to 11 could be easily conceived of by a person skilled in the art on the basis of the invention described in reference 1.

Claims: 12 to 16

Cited References: 1, 3 and 4

Notes

Reference 1 describes an implantation instrument 16 (corresponds to the "delivery device" of the present invention) comprising a discharge plunger 28 (corresponds to the "retention mechanism" of the present invention) and a filament 34 (corresponds to the "rodlike instrument" of the present invention).

The concrete structure of the filament 34 (rodlike instrument) is merely a matter of design variation. Further, when the disk is inclined, it is natural for a person skilled in the art to incline the abutment surface of the device against the disk appropriately.

Accordingly, the invention of claims 12 to 16 could be easily conceived of by a person skilled in the art on the basis of the invention described in references 1, 3 and 4.

Claims: 17 to 24

Cited References: 1, 2 and 7

Notes

The invention described in reference 2 comprises a hollow crown 40 and an annular duct 60 (corresponds to the "passage" of the present invention). (See column 6, lines 53 to 57, Figures 1 to 4.) It is deemed that the hollow crown 40 functions to raise the surrounding tissue, and thus it is deemed that it corresponds to the "upright" of the present invention.

Further, the invention described in reference 7 comprises interior bafflings 24c, 24d (correspond to the "upright" of the present invention). (See column 7, lines 52 to 58, Figure 1.)

Accordingly, the invention of claims 17 to 24 could be easily conceived of by a person skilled in the art on the basis of the invention described in references 1, 2 and 7.

List of Cited References

1. Japanese Unexamined Patent Publication (Kohyo)
No. 5-502811
2. United States Patent No. 4402681
3. European Patent Application Publication No. 606188
4. Japanese Unexamined Patent Publication (Kokai)
No. 3-292953
5. WO 94/21443
6. United States Patent No. 5000731
7. United States Patent No. 5370607

Records of Results of Prior Art Search

Technical Fields Searched: IPC 7th Ed.

A61F2/14, A61F9/00